REMARKS/ARGUMENTS

Applicant has amended claim 1 to clarify the claim language, and has withdrawn claims 27, 29, 30, 32, 35, 36, and 38 as drawn in whole or in part to a non-elected species, without prejudice to applicant's rights to pursue these claims in another application. Claims 27, 30, 33 and 36 are withdrawn since removal of non-elected species, with traverse, from these claims rendered them identical to claims 28, 31, 34 and 37. Accordingly, claims 1, 2, 21, 22, 23-26, 27(a), 28, 30(a), 34, 36 (part (a)(i)-c(i)) and 37, as amended, are pending in the present application.

Restriction and Species Election Requirement

In the August 18, 2006 Office Action, the Examiner withdrew the May 23, 2006 Restriction Requirement, agreeing with Applicant's argument that the immunogenic polypeptides of 73, 80, and 83 kDa molecular weight are to be combined and used together. However, the Examiner maintained the species election requirement because the species, defined as various protein products, allegedly are independent or distinct. Accordingly, the Examiner has placed claims 1, 2, 21, 22, 23-26, 27(a), 28, 30(a), 31, 33(a), 34, 36 (part (a)(i)-c(i)) and 37 under examination, and has withdrawn claims 27 (part b), 29, 30 (part b), 32, 33 (part b), 35, 36 (part ii a, ii b and ii c), and 38 from further consideration as being drawn to a nonelected species. Applicant has withdrawn, without

prejudice, claims 27, 30, 33, 36 because removing non-elected species from these claims renders them practically identical to pending claims 28, 31, 34 and 37. Accordingly, claims 1, 2, 21, 22, 23-26, 28, 31, 34 and 37 are now pending in the subject application.

Rejection of claims under 35 USC §112, second paragraph

The Examiner rejects claims 1, 2, 21, 22, 23-26, 27(a), 28, 30(a), 31, 33(a), 34, 36 (part (a)(i)-c (i)) and 37 under 35 U.S.C. 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner maintains that certain phrases in these claims need clarification to define the invention.

The Examiner alleges that claim 1 is vague and indefinite because it is unclear what the term "interferes" means in the phrase, "interferes with at least one of the following interactions: a CLA and E-selectin interaction...." However, it is clear from page 43, lines 10-17 of the specification that the interference of the stated interactions results in an inhibition of T cell rolling. On page 43, lines 1-4, the specification states, "...one need not immunosuppress or eliminate T cells, but rather one can provide an immunostimulator, as illustrated by the blastogenic assay reported in Tables 11, 12, 13 and 14." Therefore, in contrast to the Examiner's interpretation, interference with these interactions does not

necessarily "encompass an inhibition" but may encompass immunostimulation of T cells. Applicant therefore maintains that the specification clearly defines the term "interfere."

The Examiner also alleges that claim 1 is vague and confusing due to the phrase "a human susceptible to the symptoms of psoriasis" The Examiner questions whether the method is intended to abate symptoms of psoriasis in patients already suffering from the disease. Since humans susceptible to symptoms of psoriasis would include those suffering from the disease, it is clear that claim 1 covers patients already suffering from psoriasis. However, since the application covers treatment of psoriasis and related maladies (page 43, lines 10-14), and to simplify and clarify the claim, applicant has amended claim 1 to replace the phrase in question with the term used originally, which was "host." Since claim 1 was originally filed with the term "host," this amendment adds no new matter to the application.

Finally, the Examiner alleges that claims 21, 22, 23-26, 27(a), 28, 30(a), 31, 33(a), 34, 36 (part (a)(i)-c(i) and 37 are vague and confusing because it is unclear whether the claimed methods intend to use isolated proteins or a protein extract as claimed in parent application 09/809,003, now U.S. Patent No. 6,673,351. According to the Examiner, a purified protein extract can continually change depending on the method used to isolate it from the killed amastigote

cells, and therefore the extract should be defined as recited in claim 1 of U.S. Patent No. 6,673,351.

U.S. Patent No. 6,673,351 is directed to immunotherapeutic agents that abate psoriasis, whereas the present continuation-in-part application is directed to methods of inhibiting T-cell rolling using a compound that interferes with a mechanism of action crucial to T-cell rolling. The present application provides additional information on pages 41-45 regarding the association between this mechanism and psoriasis or related maladies such as rheumatoid arthritis. Since the present application is directed to methods of using any compounds that inhibit T-cell rolling, not to the specific compounds themselves, these compounds are adequately described as any "compound that interferes with at least one of the following interactions: a CLA and E-selectin interaction, a LFA-1/ICAM interaction or a VLA/VCAM interaction." Claim 21 describes these compounds in more detail, providing key characteristics such as their derivation from *Leishmania*, and their molecular weights. Accordingly, Applicant maintains that claim 21 and claims dependent thereon adequately define the agent to be used in the claimed methods.

In view of the above arguments and amendments, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of the pending claims under 35 U.S.C. §112, second paragraph.

Claim Objections

The Examiner noted that removal of non-elected species from claims 27, 30, 33 and 36 will result in duplicate claims, i.e., 28, 31, 34 (not 35 as stated by the Examiner), and 37. In response, Applicant has withdrawn claims 27, 30, 33 and 36 from consideration without prejudice to pursue those non-elected species of such claims in another application.

In view of the above discussion and amendments, applicant respectfully requests the Examiner to reconsider and withdraw the objection to claims 27, 30, 33 and 36 under 35 U.S.C. §112, second paragraph.

Rejection of claims under 35 U.S.C. §112, first paragraph

The Examiner also rejects claims 1, 2, 21, 22, 23-26, 27(a), 28, 30(a), 31, 33(a), 34, 36 (part (a)(i)-c(i)) and 37 under 35 U.S.C. 112, first paragraph, alleging that the specification does not enable any person skilled in the art to which it pertains to make and/or use the invention. Specifically, the Examiner maintains that the specification does not provide enablement for a method for selectively inhibiting T-cell rolling in a human susceptible to symptoms of psoriasis using any compound that interferes with at least one of the interactions listed (CLA and E-selectin, LFA-1/ICAM interaction or a VLA/VACM interaction), and that it would take undue experimentation to make and/or use the invention as claimed.

Applicant maintains that the specification enables a person skilled in the art to make or use the invention claimed in the present application. It is well established law that a specification need not contain a working example of every embodiment of the invention if the invention is disclosed in such a manner that one skilled in the art would be able to practice the invention. In contrast to the Examiner's allegation that the specification fails to demonstrate that any one immunotherapeutic agent in the specification specifically interfered with at least one of the interactions: CLA and E-selectin, LFA-1/ICAM or VLA/VCAM interaction, Examples 14 and 15 of the present application demonstrate that the claimed agent induces a TH1 response, not humoral immunity or a TH2 response. The assays shown in Tables 11, 12, 13, and 14 indicate that the polypeptides of the invention inhibit lympoid cell traffic from the blood to the skin, and from the blood to the synovial membrane. Since the specification also shows that interference with CLA-E selectin, LFA-1/ICAM and VLA/VCAM interactions is the mechanism by which such lymphoid cell traffic is inhibited, a person of ordinary skill in the art would be able to practice the invention without undue experimentation.

In view of the above discussion, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of the pending claims under 35 U.S.C. §112, first paragraph.

Rejection of claims under 35 U.S.C. §102(a)

The Examiner also rejected claims 1 and 2 under 35 U.S.C. 102(a) as allegedly anticipated by Pariser, David M., *Managed Care*, December 2003, pp. 50-56 ("Pariser"). The Examiner maintains that the claimed subject matter, i.e., inhibiting T-cell rolling by inhibiting the listed interactions, is new matter presented as part of this continuation-in-part application, and therefore is not entitled to the priority date of the parent or grandparent applications.

Pariser does not teach each and every aspect of the claimed invention. Although Pariser describes LFA-1/ICAM interactions, this reference does not describe agents that interfere with CLA-E selectin or VLA/VCAM interactions as claimed in claim 1 of the present invention. Therefore, Pariser cannot anticipate the present application under 35 U.S.C. 102(a), since it does not teach each and every aspect of the pending claims.

Furthermore, Pariser is directed to immunosuppressant agents, as demonstrated by the statement on page 1, last paragraph, "[T]he new understanding that psoriasis is an immune system dysfunction has promoted interest in developing better immunosuppressants -- specifically, biologic agents." In contrast, the

present application is directed to the use of agents that may act through a mechanism of immunostimulation. On page 42, line 25 to page 43, lines 1-4, the specification states that to treat any malady that "arises from the activity of lymphocytic infiltrate one need not immunosuppress or eliminate T cells, but rather one can provide an immunostimulator, as illustrated in the blastogenic assay reported in Tables 11, 12, 13 and 14..." The specification further discloses that stimulation of a T cell clone induces a novel cytokine, which interferes with the CLA-E selectin, LFA-1/ICAM and/or VLA/VCAM interactions (page 43, lines 10-17). In fact, Pariser teaches away from the present invention by teaching one to use agents such as monoclonal antibodies to bind to various antigens associated with T-cells or T-cell activation to immunosuppress the system rather than agents to stimulate the system. The present invention thereby provides a novel, innovative approach using immunostimulatory agents rather than the immunosuppressive agents described by Pariser to treat psoriasis and related conditions.

In view of the above arguments, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection under 35 U.S.C. 102(a).

Conclusion

Applicant believes the claims have been placed in condition for allowance by this amendment, and earnestly solicits early and favorable action by the Examiner. If

the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (973) 597-6170. The undersigned also may be contacted via e-mail at blubit@lowenstein.com.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,

Lowenstein Sandler PC

By:

Date: 12/18/06

Beverly W. Lubit, Ph.D.
Attorney for Applicant
Registration No.47,759

DOCKET ADMINISTRATOR
LOWENSTEIN SANDLER PC
65 Livingston Avenue
Roseland, NJ 07068

BWL/LSW/lz